Arizona Medical Board

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OFFICE BASED SURGERY STAKEHOLDER'S MEETING
Held at 9:00 a.m. on Monday, March 5, 2007
9535 E. Doubletree Ranch Road · Scottsdale, Arizona

Staff Members
Timothy Miller, J.D., Executive Director

PUBLIC FORUM DISCUSSION

Timothy Miller, J.D., Executive Director opened the meeting at 9:00 a.m. and opened the floor for discussion and suggestions regarding the draft Office Based Surgery Rules ("OBS Rules").

Karen Connell, Mutual Insurance Company of Arizona (MICA) suggested making changes to R4-16-101 – Definitions to make the definition of "discharge" more complete. She suggested inserting or modifying the language to incorporate the concept of the release from the office or facility of a patient who has met the criteria for recovery from the surgical procedure. For example: discharge means written or electronically documented release from the office or facility of a patient who has met the criteria for recovery from the surgical procedure. . Timothy C. Miller, J.D., Executive Director clarified that there should be documentation of actual discharge and the patient meets some predetermined criteria to be ready for discharge.

Ms. Connell suggested changing the definition of "emergency drug" to incorporate concept of drug administered in response to an emergency. She suggested "emergency drug" means a drug that is administered to a patient in response to an emergency.

Ms. Connell asked that the definition of "informed consent" to include consent that may arise out of the office based setting itself. For example, "Possible benefits and complications from the office based surgery using sedation, including those that may arise out of the office-based surgery setting." Mr. Miller stated that when drafting the OBS definition, the purpose was to obtain consent for the procedure itself as well as informed consent for the facility itself and he will work to clarify this in the Rule.

Ms. Connell stated the definition of "sedation" was unclear and she was concerned that the minor sedation definition in the Rule muddies the water. Drugs used for anxiolysis, such as diazepam, beta blockers or antihistamines would not require the same degree of monitoring as outlined in the Rule. Sedation means moderate or deep sedation as defined by the American Society of Anesthesiologists (ASA). Mr. Miller stated the statute that authorizes the Board to write rules focuses on sedation and not the method of delivery and one cannot draw a line between the different types of sedation. The intent the Rule is to regulate the administration of medication for the purposes of sedation for surgery. MICA was concerned that the Rules would set too high a standard for minor sedation used to relax a patient. Mr. Miller stated Staff has struggled with this. The Rules were not meant to codify a standard of care. If the standard of care is higher than what is stated in the Rules, then the Board would hold a physician to the higher standard of care. There is a dual analysis between what is considered the standard of care and what is within the scope of the Rules.

Under R4-16-703 – Procedure and Patient Selection, section (B)(1) Ms. Connell stated the term "undue" is hard to define as a complication of a medical condition. She asked that the Board consider modifying this section as follows: "…that poses an increased risk of complications not disclosed to and discussed with the patient or". Mr. Miller stated the intent was for surgeons not to select procedures that are not likely to have inpatient recovery. This language needs to be clarified in the Rule. Ms. Connell also stated that the language section (B)(3) implies a level of prediction that may not be achievable. She suggested changing this language to "May reasonably be expected to require services at a hospital."

Ms. Connell stated that in R4-16-704 – Sedation Monitoring Standards if the definition minimal sedation" is removed from the definition of "sedation" as recommended, then paragraph one, "When administering minimal sedation, use a quantitative method of assessing the patient's oxygenation, such as pulse oximetry" be deleted. Ms. Connell said it sets too high a standard to require pulse oximetry for all types of sedation.

R4-16-705 – Perioperative Period; Patient Discharge. Ms. Connell asked for what period of time does the physician have to stay with the patient under section (1). She stated section (2) implies the physician remains in the building until discharge and asked if this was the intent. Mr. Miller stated a physician could leave the facility when monitoring is completed. Ms. Connell stated Advanced Cardiac Life Support (ACLS) training is required for staff in physicians' offices that perform minimal sedation; however, some staff, such as medical assistants, are not eligible to become ACLS trained. Mr. Miller stated he knows that the physician will be using non-licensed staff during some procedures and he is working on this issue. Ms. Connell

suggested that maybe minimal sedation could have different language than moderate sedation. In section (4) Ms. Connell suggested inserting "currently" certified in ACLS. She also noted there should be a higher level of oversight with moderate or deep levels of sedation, yet the language mirrors that for minimal sedation, implying that a staff member could monitor the patient in the absence of a physician in contradiction to the statement that the physician must be present in the office until the monitoring is discontinued. Ms. Connell also suggested that in section (5)(b) there should be mention of established criteria being met for discharge.

Ms. Connell said that in R4-16-706 – Emergency Drugs; Equipment and Space Used for Office-Based Surgery Using Sedation, section (A)(1)(c), there is no mention of endotracheal intubation and language to this effect would be useful since airway problems requiring this intervention are a common source of difficulty, even prior to the need for defibrillation.

Ms. Connell also suggested adding an item to this effect: If a physician who performs office-based surgery using sedation expects or intends to use an agent for which there is no antagonist, such as Propofol/Diprivan, the physician shall ensure that equipment and medication necessary for supporting ventilation and circulation is available until the effects of the drug have dissipated or the patient is transferred to a medical facility before the physician performs the office-based surgery using sedation. Ms. Connell stated this has been a concern both locally and in the medical literature.

Jeff Mueller, President, Arizona Society of Anesthesiologists (AZSA) stated his first concern was with the definition of "deep sedation." He recommended the definition be changed to "a drug induced depression of consciousness during which patients cannot be easily aroused, but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained." Mr. Mueller stated this is a commonly accepted definition. Mr. Miller stated that the Board purposefully left out that the patient may require assistance. Mr. Mueller noted there is chart form of these definitions that makes them easier to identify.

In R4-16-704 – Sedation Monitoring Standards, Mr. Mueller suggested there be a separate requirement for ventilation monitoring as part of section (2)(d) to "monitor ventilation by observation, auscultation, capnography, or other reliable forms of apnea monitoring. He stated that "ventilation" is a medical specific word and the word "breathing" equates with the medical word "ventilation." The current rule does not require monitoring of the patient's breathing in an office-based surgery setting and a Rule without such requirement is incomplete and dangerous. He suggested accepting the above language and renumbering (2)(d) to (2)(e). Mr. Mueller said that discussing the difference between oxygenation and ventilation is necessary. A patient can be apneaic, but as long as the patient has a mask, the patient's ability to rid of carbon dioxide is impaired. A provider needs to make sure the patient is breathing. There are monitors for this including pulse oximetry and clinical monitoring. Mr. Miller stated there were three primary areas of patient safety addressed in the Rule, including equipment, support staff, and policies and procedures for emergencies. Monitoring for ventilation is also an important area. Mr. Mueller stated the ASA has a well developed set of practice parameters that should be included in the standard and he placed emphasis on this comment.

Mr. Mueller asked that the Board consider language his organization previously submitted as it relates to R4-16-704 (2)(b)(iv) to state "Monitor temperature when clinically significant changes in body temperature are intended, anticipated, or suspected." He stated the current wording alters the meaning of their previously submitted language. This is the basic ASA monitoring standard and may remove an unnecessary burden on providers in some circumstances.

Mr. Mueller stated the language pertaining to malignant hyperthermia has been retained in the R4-16-707. This is unnecessary language in a Rule pertaining only to sedation. The proposed language is misleading and may inadvertently lead a physician to believe the use of such agents is permitted during sedation if the appropriate equipment and agents are available to treat MH. Practice that treats MH is unnecessary in his opinion. Malignant hyperthermia ("MH") is a result of a combination of volatile anesthetics and succinylcholine that paralyzes a patient. Today, there is no sedation with volatile agents, with the exception of nitrous oxide, which does not trigger MH. Succinylcholine is given intravenously after the patient has been anesthetized. Propofol is also given intravenously and does not trigger MH. It is unnecessary to require a practice to have the ability to treat MH because those practices should not be using the drugs that trigger MH.

Mr. Mueller stated the proposed Rule has no language regarding rescuing a patient from sedation deeper than intended. The Rule must state that those administering anesthesia have the ability to rescue from a deeper sedation than intended and the absence of such a statement would result in a deficient and uninformed Rule. It is not possible to give a patient moderate sedation and not have an occasion where the patient transitions into deeper sedation. Mr. Mueller feels strongly about this item and it is a core concept of safe sedation and a part of the national guidelines and practice parameters. One cannot precisely titrate sedatives to get the exact desired result every time. Mr. Mueller's personal experience is that Propofol is a difficult drug to titrate and can quickly become a general anesthetic, especially in untrained hands. Mr. Miller said we received some comments asking to ban Propofol from the list of agents used, but chose not to identify individual drugs. Mr. Mueller reiterated that providers need to be ready for a higher degree of anesthesia than intended.

Mr. Mueller stated that although proposed Rule requires training in ACLS if moderate or deep sedation is performed, there is no explicit requirement that facility have all the needed resuscitative equipment needed to carry out ACLS. He suggested adding "Resuscitation equipment, including a defribulator and all other equipment necessary to follow ACLS and PALA guideline to R4-16-706 – Emergency Drugs; Equipment and Space Used for Office-Based Surgery Using Sedation.

Mr. Mueller stated that R4-16-703 – Procedure and Patient Selection, limits office based surgical procedures to those that allow the patient to be discharged from the physician's office within 24 hours, implying that procedures that normally require an overnight stay in a hospital are appropriate as an office based surgical procedure. Procedures of such complexity should not be carried out in the unlicensed office based setting. These are collective concerns among his Board and officers. Mr. Miller stated that the Arizona Department of Health Services (ADHS) has two limitations for offices that practices that do not require a license. There is a current bill to further define which offices can be considered private practices not requiring licensure. The way this Rule is written may provide a loophole for physicians to evade both the ADHS and Arizona Medical Board jurisdictions. Mr. Miller will discuss the issue of overnight stays with ADHS. Mr. Mueller clarified that there may be an opportunity to have the Rule apply to situations where the patient does not stay overnight, but avoid a gap between the OBS Rules and the ADHS licensure requirements.

Under R4-16-702 – Administrative Provisions, section (A)(2) and R4-16-704 – Sedation Monitoring Standards, section (2)(d), AZSA recommends, because of the risks of planned deep sedation, privileges to administer deep sedation be given only to those practitioners qualified to administer general anesthesia or to appropriately supervised anesthesia professionals. The proposed Rules for healthcare professionals allows for inadequately trained individuals to administer deep sedation. Mr. Miller clarified that AZSA feels the Rules do not set the bar high enough. Mr. Mueller stated the definition of deep sedation is very gray when applied to the practical perspective. There are some, including himself, who believe the concept of deep sedation has more administrative and policy significance than practical application. Public safety is an issue and a practitioner who goes in with the intent to administer deep sedation has to prepare for dealing with a patient who transitions into general anesthesia. Mr. Miller stated when a physician uses deep sedation, he or she, as well as the staff, needs to be qualified to use general anesthesia. Mr. Mueller did not find there is a difference between the ability to provide general anesthesia from the ability to rescue someone from general anesthesia. This issue frequently comes up in other states and other settings.

Mary Wojnakowski, CRNA, Ph.D., President, Arizona Association of Nurse Anesthetists (AZANA) stated she appreciated the approach the Board has taken to stakeholder involvement in the OBS Rules. She referred to R4-16-704 – Sedation Monitoring Standards and requested a change that would provide clarification to the role of the operating physician while considering the authority of the Board. The current language reads as though the physician performing surgery is also administering the sedation. This is a practice not consistent with the national standards of care, particularly with moderate or deep sedation. For instance in 704(A)(1) regarding a physician who performs office, change the language to state "When minimal sedation is administered ensure use of a quantitative method of assessing patient oxygenation such as pulse oximetry. When moderate or deep sedation is administered, ensure the following: a quantitative method of assessing patient oxygenation such as pulse oximetry utilized, so forth and so on, so that it is clear it is not the operating physician performing the anesthesia, but rather supervising anesthesia and patient oxygenation. Ms. Wojnakowski suggested more regulatory type language than what is currently in the Rule.

Ms. Wojnakowski referred to R4-16-706 – Emergency Drugs; Equipment and Space Used for Office-Based Surgery Using Sedation and stated that under this section a physician performing office-based surgery is with sedation is required to have a reliable oxygen source with a Fi02 or SaO2 monitor. She stated a SiO2 monitor is not an appropriate monitor for ensuring a reliable oxygen source. The SaO2 monitor measures a patient's oxygen saturation level. The only reliable monitor is a FiO2 monitor and an SaO2 should be required under section (1)(f) in addition to an FiO2 monitor. Miller clarified that both monitors should be used.

Ms. Wojnakowski stated they support removing section (B) regarding MH in R4-16-707 – Emergency Transfer Provisions. Neither of these agents are expected or intended to be used for sedation in any case in a physician's office.

The proposed definition of healthcare professional definition could be interpreted to indicate that a registered nurse or physician assistant is permitted to administer deep sedation in a physician's office. This practice is not congruent with national standards of care, nor with Arizona statutes and rules for governing this practice and should be restricted to licensed anesthesia providers. Ms. Wojnakowski also stated it is better to identify each healthcare professional practicing in the physician's office setting because their scopes of practice are not the same and we do not want to authorize procedures that are outside their scopes of practice. Mr. Miller agreed that the term healthcare professional was used for simplicity's sake, but we do not want to make it unclear which providers can and cannot do specific tasks. Ms. Wojnakowski stated while it is laborious to list each type of practitioner, it may eliminate the possibility of overstepping those tasks that are regulated by other boards.

Ms. Wojnakowski also provided American Association of Nurse Anesthetists' Office Based Anesthesia standards for the Board's references and encouraged the Board to incorporate some of these standards in the Rule.

Joel Wakefield, from Coppersmith Gordon Schermer & Brockelman, PLC represented the Arizona Hospital and Healthcare Association and Banner Healthcare. He expressed their support for OBS Rules. Their concern is with the application and scope of the Rules. They apply to OBS with sedation, which also applies to any medical procedure in a physician's office that is not a hospital or ASC. There are quite a few types of facilities that do not fall into a hospital or ASC setting that may also be considered an outpatient facility, regulated by ADHS, such as outpatient treatment centers, nursing care facilities, and hospice facilities. There are two concerns: (1) overlapping rules between ADHS and Arizona Medical Board and (2) the issue of consistency. If one of the licensure rules requires one thing and the other rule requires another, the facility is caught in the middle. He suggested addressing this concern through the definition of Office Based Surgery, which is overbroad. If the Board cannot change the definition, he recommended changing R4-16-702 – Administrative Provisions to state "a physician performing office-based surgery in the physician's office or other outpatient facility not licensed by the Arizona Department of Health Services shall do the following…." This will establish the delineation between ADHS licensure and Board's oversight. Mr. Miller stated this is a well taken point. The language of the pending ADHS bill states what offices are no longer part of the

exception to licensure. We need to make it clear that it is not a physician's office not licensed by ADHS in the language. Mr. Miller noted that we will probably have to make this change in R4-16-702. Mr. Wakefield did not see a problem of amending R4-16-702.

The meeting adjourned at 10:34 a.m.

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Timothy C. Miller, J.D., Executive Director